BIONOSTICS
Quality Solutions

K123966

510(k) Summary[1]

JAN 2 5 2013

(a) (1) Submitter's name, address

Bionostics, Inc.
7 Jackson Road
Devens, MA 01434

Contact Person

Randy Byrd
VP, Chief Technical Officer
(978) 862-1830

Date of preparation of this summary: 25 January 2013

(2) Device trade or proprietary name: Glucose Meter-Check® Solution for Bayer

Device common or usual name or classification name:

REGULATION NAME	CLASSIFICATION NUMBER	CLASS	PRODUCT CODE
Quality Control Material	862.1660	I, reserved	JJX

(3) Substantial Equivalence

Glucose Meter-Check Solution for Bayer is substantially equivalent in function, safety and efficacy to currently marketed devices for the same intended use:

Comparison of Glucose Meter-Check Solution to predicate devices for substantial equivalency

Similarities and Differences of the Blood Glucose Control		
Item	Predicate Device: Glucose Meter-Check Solution for Bayer K082395	Candidate Device
Intended Use/Indications for Use	Glucose Meter-Check® Solution is intended for in vitro diagnostic use to assess the performance of the Bayer blood glucose monitoring systems: Contour Next, Contour and Contour TS, and Breeze 2 by healthcare professionals and in the home by people with diabetes mellitus	Same, with the addition of Bayer Contour Next BGMS
Stability	24 Months	same
Value assignment	determined by analysis of glucose on commercial lots of glucose test strips qualified for proper measurement using manufacturer recommended control solution	same
Traceability	N.I.S.T. SRM 917	same
Target range	76 to 106 mg/dL (range of midpoint value assignment for various meter types)	94 to 135 mg/dL (range of midpoint value assignment for various meter types)

[1] This summary of safety and effectiveness is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Item	Predicate Device Glucose Meter-Check Solution for Bayer K082395		Candidate Device	
Auto QC detection	no		no	
Matrix	Ingredient (w/v%)	Current Solution	Ingredient (w/v%)	Current Solution
	Glucose	0.08	Glucose	0.11
	pH	7.15	pH	same
	Buffer	1.02	Buffer	same
	Salt	0.40	Salt	same
	Viscosity Modifier	15.0	Viscosity Modifier	same
	Preservatives	0.03	Preservatives	same
	Dye	0.05	Dye	same
Container	6 mL white LDPE		same	
Analyte	glucose		same	
Color	red		same	
Net Fill	4 mL		same	

*midpoint of assigned values, depending on meter and test strip combination

(4) Description of the new device

Glucose Meter-Check Control Solution is a viscosity-adjusted, aqueous liquid glucose control solution containing no ingredients of biological origin, or in concentrations qualifying as a controlled product under the Controlled Products Regulation. Glucose Meter-Check Control Solution is intended for use to verify the performance of the Bayer BGM systems listed in the package insert and is intended for use by healthcare professionals and people with diabetes mellitus at home. The product is packaged in plastic bottles with dropper tips for application of the solution to test strips. The control has a red color to help users see the solution while dispensing onto a test strip. Glucose Meter-Check Solution is a non-hazardous aqueous solution glucose control solution containing no ingredients of biological origin, or in concentrations qualifying as a controlled product under the Controlled Products Regulation.

Standard/Guidance Documents Referenced (if applicable):

- ISO 15197:2003 In Vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus.
- ISO 14971:2009 Medical devices – Application of risk management to medical devices
- ISO 13485:2007 Medical Devices – Quality Management Systems – Requirements for regulatory purposes
- ISO 15223-1 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General Requirements
- ISO 18113-4 In vitro diagnostic medical devices - Information supplied by the
- manufacturer (labeling) - Part 4: In vitro diagnostic reagents for self-testing
- EN 13640 Stability Testing of In Vitro Diagnostic Reagents
- Guidance for Industry and FDA Staff – Assayed and Unassayed Quality Control Material

(5) Intended use of the device

Glucose Meter-Check Solution for Bayer is intended to assess the performance of the following Bayer blood glucose test systems:

- Bayer Contour Next blood glucose monitoring systems
- Bayer Breeze 2 blood glucose monitoring systems
- Bayer Contour and Contour TS blood glucose monitoring systems

Glucose Meter-Check Solution for Bayer is intended for use by healthcare professionals and people with diabetes mellitus at home.

(6) Technological characteristics of the device.

This material consists of viscosity-adjusted, aqueous glucose control solution prepared with a single concentration of D-glucose and has been optimized to simulate the response of whole blood on Bayer blood glucose test systems. The solution contains no hazardous, human or animal derived components.

Test Principle:

The BGMS with which this control solution is utilized utilize enzymatic measurement of glucose

(b) (1) Summary of non-clinical tests submitted with the premarket notification for the device.

Tests were conducted to verify specific performance requirements:

a) Closed bottle stability

Stability characteristics were determined under un-opened conditions in real time stability studies of equivalent product to demonstrate an unopened shelf-life of 2 years (24 months) at the recommended storage temperatures, ranging from 2°C to 30°C (36°F to 86°F)

b) Stability after opening

Glucose Meter-Check Solution for Bayer meets stability requirements as demonstrated by less than 5% change in percent glucose recovery on YSI on vials evaluated of 3 months (93 days).

c) Method comparison with predicate device:

Current version blood glucose meters, test strips and quality control solutions were purchased through retail outlets for Bayer blood glucose monitoring systems. To evaluate equivalence, we performed a series of measurements at room temperature on two Infopia meters using the Glucose Meter Check Solution followed by mid-level Bayer quality control solution for each strip/meter type. Specific Bayer-branded control solutions are recommended for use with all current Bayer-branded glucose meters based upon the test strip brand used with each meter.

The individual values obtained on each measurement were compared to the relevant value assignment ranges for meter/test strip/control combination as well as to the value assignment ranges determined as described above for the Meter-Check control solution calculated as mean recovered from 3 test strip lots ± 11% (Contour Next) or ± 16% (Contour, Contour TS and Breeze2) to correspond to the value assignment ranges currently utilized by Bayer for the meters using the relevant Bayer-branded test strips.

Detailed results are provided in Table 2: Evaluation of Equivalence of Control Solutions on the following page. Each quality control solution was measured in series as described above on each of the Bayer test systems.

The Acceptance Criteria (at least 95% of measurements obtained for the manufacturer recommended quality control solution were within the value assignment ranges provided on the test strips for that meter, test strip and control solution combination) were met with 100% of all values recovered within value assignment ranges provided with each vial of test strips. 100% of Meter Check measurements on the same meter and test strip combination were within the value assignment ranges established for Meter Check.

Test Strip Type	Meter Brand	Control Brand	Pooled Mean	Pooled SD	Pooled CV%	assay range (mg/dL)	assay range (%)	within assay range
Breeze 2	Breeze 2	Breeze 2	111.9	4.4	4.0%	93 – 127	15%	100%
		Current Meter-Check	111.5	2.8	2.5%	95 – 128	15%	100%
		New Meter-Check	127.2	3.2	2.5%	111 – 151	15%	100%
Contour	Contour	Contour	123.6	3.3	2.6%	104 - 144	16%	100%
		Current Meter-Check	72.3	4.8	6.7%	60 - 84	16%	100%
		New Meter-Check	117.0	6.3	5.4%	102 – 140	16%	100%
Contour TS	Contour TS	Contour TS	119.7	1.4	1.2%	102 – 140	16%	100%
		Current Meter-Check	79.2	4.5	5.7%	67 - 92	16%	100%
		New Meter-Check	120.0	5.4	4.5%	102 – 140	16%	100%
Contour Next EZ	Contour Next	Contour Next	130.8	2.9	2.2%	116 - 144	11%	100%
		Current Meter-Check*	103.5	2.5	2.4%	92 - 115	11%	100%
		New Meter-Check	121.0	1.7	1.4%	110 - 138	11%	100%

Table 2: Evaluation of Equivalence of Control Solutions

* Value assignment for Contour Next EZ determined on Current Meter-Check as mean ±11% to correspond to value assignment range determined by test strip manufacturer.

Greater than 95% (100%) for all measurements of Meter-Check Control Solution were found to be within these limits and therefore, the acceptance criteria are met.

(b) (2) Summary of clinical tests submitted with the premarket notification for the device.

N/A

(b) (3) Conclusions drawn from the clinical and non-clinical trials.

Comparison of technological characteristics, formulation and intended use to predicate devices listed in this summary support the claim of substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 25, 2013

Bionostics
Mr. Randy Byrd
7 Jackson Road
Devens, MA 01434

Re: k123966
Trade/Device Name: Glucose Meter-Check Solution for Bayer BGM Systems
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material
Regulatory Class: I, reserved
Product Code: JJX
Dated: December 20, 2012
Received: December 26, 2012

Dear Mr. Byrd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carol C. Benson for

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K123966

Device Name: Glucose Meter-Check Solution for Bayer

Indications for Use: Glucose Meter-Check Solution Bayer is intended to assess the performance of the following Bayer blood glucose test systems:

- Bayer Contour Next blood glucose monitoring systems
- Bayer Breeze 2 blood glucose monitoring systems
- Bayer Contour and Contour TS blood glucose monitoring systems

Glucose Meter-Check Solution for Bayer is intended for use by healthcare professionals and people with diabetes mellitus at home.

For *In Vitro* Diagnostic Use

Prescription Use ✓ (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ✓ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

Katherine Serrano
2013.01.24 09:36:03 -05'00'

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k123966